

Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health Pittsburgh Research Laboratory P.O. Box 18070 Pittsburgh, PA 15236-0070

September 30, 2003

Kenneth Olden, Ph.D.
Director
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, North Carolina 27709

Dear Dr. Olden:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) toxicological test recommendations on *in vitro* methods for acute systemic toxicity and the revised Up-and-Down Procedure (UDP) per your letter dated March 21, 2003. NIOSH is not an agency which "carries out a program that requires or recommends acute or chronic toxicological testing" as stipulated under Section 4(a) of Public Law 106-545, and as such is not required to report. However, NIOSH is a member agency of ICCVAM, and strongly supports the adoption of validated alternative tests. NIOSH concurs with the ICCVAM test method evaluation that both of these test methods are valid; the *in vitro* method can be used to select an appropriate starting dose for acute toxicity tests, and the UDP can be used instead of the conventional LD50.

NIOSH does not currently conduct acute oral toxicity testing, and thus the test methods are not directly applicable to NIOSH programs. However, we will notify all NIOSH personnel of the availability of the new test methods via agency-wide intranet notices and agency news letters. NIOSH's Health Effects Laboratory Division does conduct toxicity testing and may apply information provided by tests that have been acted on by ICCVAM.

In addition, NIOSH will post a notice of concurrence with these ICCVAM test recommendations on our internet Web site so that outside agencies or institutions that contribute data or results considered by NIOSH in evaluations of hazards or risk assessments will be notified of NIOSH's endorsement of these two test methods.

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Thank you for providing these first two ICCVAM toxicological test recommendations for our review.

Sincerely yours,

/s/

John Howard, M.D. -Km

Director